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| PRE-APPEAL BRIEF REQUEST FOR REVIEW | | Docket Number (Optional) | | | | | | | | | | | | | | | | | |
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| <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on _____</p> <p>Signature _____</p> <p>Typed or printed name _____</p> | | Application Number | Filed | | | | | | | | | | | | | | | | |
| | | 08/981,665 | November 5, 1997 | | | | | | | | | | | | | | | | |
| | | First Named Inventor | | | | | | | | | | | | | | | | | |
| | | CIPKOWSKI | | | | | | | | | | | | | | | | | |
| | | Art Unit | Examiner | | | | | | | | | | | | | | | | |
| | | 1641 | Grun, James Leslie | | | | | | | | | | | | | | | | |
| <p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <table border="0"><tr><td><input type="checkbox"/> applicant/inventor.</td><td></td></tr><tr><td><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</td><td>Signature</td></tr><tr><td><input checked="" type="checkbox"/> attorney or agent of record. Registration number 31877</td><td>B. Aaron Schulman</td></tr><tr><td></td><td>Typed or printed name</td></tr><tr><td><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</td><td>703-739-4900</td></tr><tr><td></td><td>Telephone number</td></tr><tr><td></td><td>March 9, 2009</td></tr><tr><td></td><td>Date</td></tr></table> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input type="checkbox"/> *Total of _____ forms are submitted.</p> | | | | <input type="checkbox"/> applicant/inventor. |  | <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) | Signature | <input checked="" type="checkbox"/> attorney or agent of record. Registration number 31877 | B. Aaron Schulman | | Typed or printed name | <input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____ | 703-739-4900 | | Telephone number | | March 9, 2009 | | Date |
| <input type="checkbox"/> applicant/inventor. |  | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) | Signature | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> attorney or agent of record. Registration number 31877 | B. Aaron Schulman | | | | | | | | | | | | | | | | | | |
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This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicants submit this paper in an effort to avoid the need for further Appellate proceedings in light of the fact that invention as presently claimed is adequately disclosed in the specification, and that none of the references singly or in combination disclose or make obvious the elements of Applicants' claimed invention. Moreover, as shown below, the main reference cited by the Examiner actually **teaches away** from the present claims and discloses a configuration that is opposite to Applicants' claimed invention. Applicants thus submit that the pending rejections are improper and should be withdrawn for at least the reasons are provided below, and Applicants hereby request a pre-appeal review of these rejections and the subsequent withdrawal of those rejections.

In the most recent Official Action, there were only two substantive rejections, one under Section 112, first paragraph, on the basis of the written description requirement, and one under Section 103(a) on the basis of obviousness. As set forth below, neither of these references are warranted, and both should be withdrawn as improper.

With regard to the Section 112, first paragraph rejection, the Examiner rejected Claims 16, 18 and 19 as allegedly unsupported in the specification. With all due respect to the Examiner, this rejection is completely unfounded, as was pointed out in an interview between Applicants' representative, the Examiner and Supervisor. In particular, Claim 16 is directed to an immunoassay test card which houses one or more test strips, and the test card features a front surface having openings which expose (1) the sample contacting portion of the test strip and (2) the test portion of the test strip. Applicants' disclosure, as reflected for example in Figs. 9-11, shows, not surprisingly, a test card designed to house a conventional immunoassay test strip, and the test strip

has (1) openings (element 51) which expose the sample contacting portion of the test strip and (2) openings (element 50) which expose the test portion of the test strip. This is made perfectly evident in the accompanying text of the specification at page 12, lines 4-9, which recites:

. . . The top ply 47 is provided with a plurality of test windows 50¹ through which the test results as indicated by the test strips can be seen. At the lower end of the card are provided sample openings 51 through which the liquid test specimen is able to contact the absorbent or sample portions of the test strips.

As was indicated in the Interview, the Examiner's only position on this rejection was that Applicants' specification described conventional immunoassay test strips, some of which may not have had a surface which would have been exposed by the sample opening in the test card. However, such a position is completely unfounded. In the first place, to the extent Applicants' specification disclosed standard or conventional test strips, including those (such as described in the present application) which have a sample contacting portion on the front surface, such a disclosure adequately supports the claims even if other conventional test strips somehow have a different configuration.

Moreover, it is clear from the present specification that a flat test strip is described which contains a sample contacting portion which is exposed by the lower opening 51 in the claimed test card and a test portion (for displaying the results of the immunoassay test) which is exposed by the test openings in the claimed test card. These elements of the claims are thus completely and accurately disclosed in Applicants' specification, and a rejection under 35 U.S.C. §112, first paragraph, on the basis of lack of written description is entirely improper and should be withdrawn.

¹ Later on that same page, element 50 is referred to as "test **openings** or windows 50". See pg. 12, lines 15-16.

The other remaining substantive rejection was a rejection of the claims under 35 U.S.C. §103(a) on the basis of May et al. PCT reference WO 88/08534 (“May”) in view of Sun et al. US 5,238,652 (“Sun”), and further in view of Boger et al. US 4,518,565 (“Boger”). As indicated below, this rejection is similarly flawed because the main basis for the rejection, namely the notion that May discloses the basic configuration of Applicants’ claimed test card, is incorrect. Moreover, as shown below, the May reference takes steps to **avoid** the configuration as described in Applicants’ claims, and thus completely **teaches away** from the present invention.

In particular, in the outstanding Official Action, the Examiner asserted that the May reference disclosed the actual configuration of the test card of the present claims, namely one which has a sample opening directly exposing a sample contacting portion of a test strip included in the claimed test card, along with a test opening directly exposing the test portion of the test strip. For reasons as explained in detail below, this is simply not true.

Further, the Examiner went on to indicate that the Sun reference would teach “constructions wherein antigen in sample and antigen immobilized on the test strip compete for binding with mobile latex-labeled antibodies” and that Boger taught “reagent area-exposing openings in a holder . . . for holding multiple test strips.” See Final Rejection, page 7. However, the Examiner’s recitation of the teaching of the Sun and Boger references shows that these references have nothing to do with the claimed subject matter and cannot be combined with May to make the present claims unpatentable, even, assuming *arguendo*, that the May reference had disclosed the basic configuration of the claimed test strip, which is not the case.

More particularly, in total contrast to the present invention wherein the test card is configured with an opening directly over the sample contacting portion of the test strip, the May reference only discloses devices wherein a fluid sample is only brought into contact with the test strip at its edges. This is made evident if one looks at the drawing figures in the May patent reference, not a single one of which discloses an exposed opening of the sample receiving portion of the test strip wherein the fluid sample is directly contacted. To the contrary, in all of the different embodiments, the May configuration is one wherein the fluid contacts the strip at its edge, as opposed to the claimed invention wherein the fluid sample contacts the front surface of the sample contacting portion of the test strip, at which point the fluid moves along the front surface of the strip via capillary action until the sample reaches the test portion. In particular, the embodiments shown in Figs 1-5 and 13-14 have an opening only at the end; the embodiments of Figs. 6-7 have a receptacle 202 which is not directly above the test strip; the embodiment of Figs. 8-9 have openings (508-509) only for visualizing the test results; and the embodiment of Figs. 11-12 have an opening 601 which is not directly above the test strip 606. Accordingly, the May patent nowhere discloses a configuration wherein the sample contacting opening is directly over the sample contacting portion of the test strip, and instead teaches away from the claimed invention because it only discloses contacting the sample at its edge and not the sample contacting portion exposed on the front surface.

Moreover, May goes even further and **blocks** the fluid sample from contacting the test strip directly on the sample contacting portion as is done in Applicants' claimed invention. This is best shown in the embodiment of Figs 11 and 12 wherein the opening 601 is not over the test strip 606, but over a porous receiving member 605. In addition,

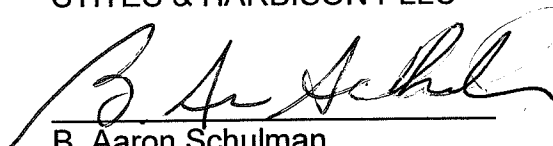
the device is set up so that the front surface of test strip is **blocked** by the covering, and instead is set up to provide a seal **against** the ingress of moisture onto the front surface of the test strip. See May reference, page 27. The teachings of May are entirely contrary to the presently claimed invention, and a fluid sample could **not** be directly applied to the surface contacting portion of a test strip in the May device even if one wanted to do so. The May reference is thus **completely contradictory** to Applicants' claimed invention, and **teaches away** from the present invention because it operates in a manner entirely opposite from the Applicants' claimed test card.

Accordingly, the May reference does not disclose or make obvious Applicants' claimed invention, and in fact teaches away from the present claims. Moreover, as indicated above, none of the other references cited by the Examiner have any bearing on the patentability of the claims, nor does the Examiner even assert that such references disclose the configuration of the claimed test card which, as shown above, is clearly not disclosed in the May reference.

In light of the foregoing, Applicants respectfully submit the Examiner's rejections are in error and should be withdrawn so that this application can be given an allowance without the need for any further Appellate proceedings. Such action is respectfully requested.

March 9, 2009

Respectfully submitted,
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